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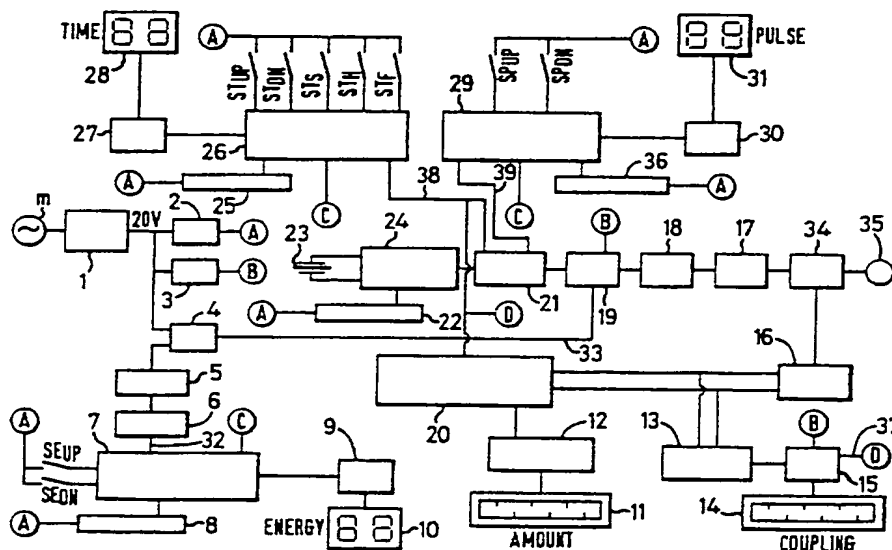
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(54) Ultrasound apparatus for non invasive cellulite reduction

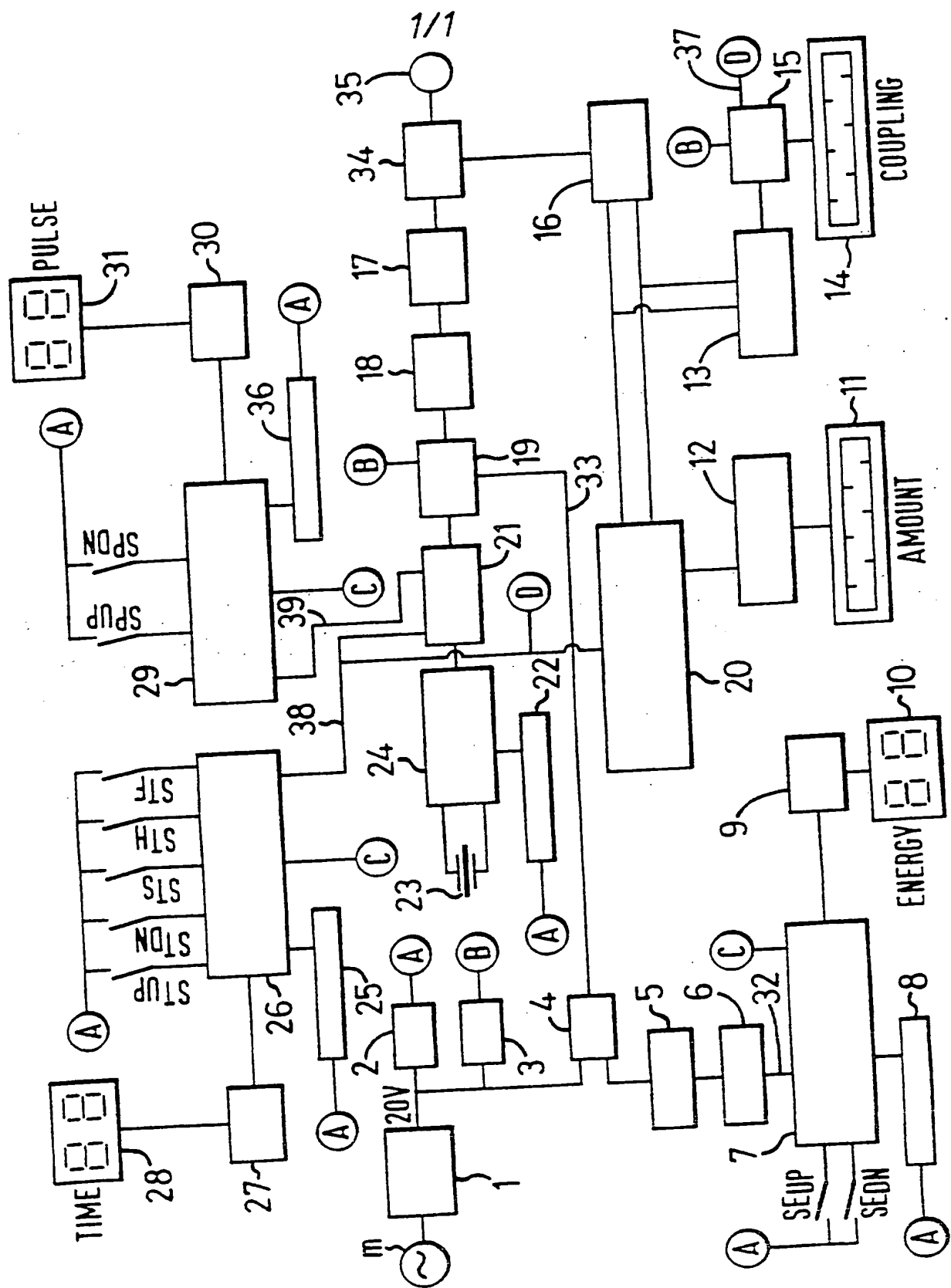
(57) The apparatus comprises an ultrasound generator with driving means 4 connected to an output synthesizer 24, output amplifiers 18, 19 and pulse control means 29. The output synthesizer 24 produces vibrations at a predetermined frequency and the output amplifier 18 controls the magnitude of vibrations supplied via an output terminal 35 to an applicator head (not shown). Output signals and pulse control means are preferably controlled by microprocessors 7, 29. The device allows the ultrasonic treatment of cellulite at a predetermined frequency of about 3.3 MHz and at a predetermined depth of about 1.27-2.54 cm from the skin surface. The pulse control means 29 modulates the predetermined frequency in an on/off fashion and thereby limits unnecessary heating of the skin or subcutaneous tissue during treatment.



GB 2 303 552 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995



NON-INVASIVE CELLULITE REDUCTION APPARATUS

The present invention relates to a non-invasive cellulite reduction apparatus.

5 In the human body, the musculature is overlaid by an outer layer comprising subcutaneous tissue and then the dermis and epidermis, the latter being the surface of the human body colloquially identifiable as the skin.

10 In certain regions of the body, particularly the tummy, upper legs and buttocks of the female human body, there is a tendency for a thickening of this outer layer. Furthermore, the thickened layers tend to have a different texture when compared with other adjacent regions of skin which are not thickened. Indeed, a rather lumpy appearance can sometimes be
15 visually discernable. It has also been noted that these thickened regions tend to have a lower skin temperature. Consequently, it will be apparent that the effects of the thickening are physically and visually detrimental.

Various dietary and exercise methods have been proposed
20 in an attempt to reduce the thickened regions. However, it has been found that they often do not respond well to even rigorous dietary and exercise methods and in addition it is difficult to target such dietary and exercise methods to the specific regions of the body. Indeed, it has been noted that
25 people with little other bodily fat still retain these thickened regions.

Research has now established that the thickened regions arise from a fat, known as cellulite, which can build up in the subcutaneous tissue. It is believed that when fat occurs
30 in the human body, it can build up as cellulite in a cell. However, the cell wall tends to become calcified as a result of incorrect diet in which case it is not then possible for the cellulite to effectively pass out through the calcified cell wall notwithstanding rigorous conditions of diet and
35 exercise.

Thus, to counter the detrimental effects of cellulite, various known invasive techniques have been developed for

reducing the amount of cellulite. Unfortunately, the use of such invasive techniques can leave traces and detrimental aftereffects.

It has therefore been proposed to use ultrasonics as a
5 technique for the non-invasive removal of cellulite. Ultrasonics or ultrasound refers to sound vibrations having frequencies beyond the human auditory limit, typically above 20 KHZ. Ultrasound can be produced in a variety of known manners, usually employing a transducer, for example a quartz
10 crystal or piezoelectric element. Whilst ultrasound energy would seem to disrupt the calcification of the cell enabling cellulite to pass out of the cell, the technique has not hitherto been wholly successful or effective.

It is therefore an object of the present invention to
15 provide a non-invasive cellulite reduction apparatus that is more successful and effective both in terms of efficiency and utility.

According to one aspect of the present invention there is provided a non-invasive cellulite reduction apparatus
20 comprising:-

an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations
25 to a human surface in contact with a surface of the applicator means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said transferred ultrasound vibrations are absorbed within a
30 predetermined depth of said human surface; and

energy level control means for controlling the magnitude of said ultrasound vibrations.

By having an energy level control means, it is possible for an operator of the apparatus to simply, efficiently and
35 effectively control the level of ultrasonic energy at the applicator head for application to the human surface (the skin) so as to optimise the reduction of cellulite.

Furthermore, it has been found that the effectiveness of cellulite reduction is proportional to the square of the power transferred into the tissue. Thus, by controlling the energy level, the effective reduction in cellulite can be significantly altered thereby allowing targeted and selective reduction of cellulite according to the region effected and the degree to which it is effected by cellulite.

Preferably, said predetermined frequency is manually settable.

By having the frequency manually settable, it is possible to target the depth of penetration into the human surface thereby controlling where the ultrasound vibrations interact. This enables controlled reduction of the cellulite.

In a preferred embodiment of the invention the predetermined frequency has a value of 3.3 MHZ \pm 0.5 MHZ.

By having such a value, the apparatus is automatically set to a preferred frequency for general operation whilst retaining flexibility of operation. The lower the frequency, the deeper the penetration and the higher the frequency the more the actual human surface is heated.

Conveniently, said major portion comprises 50% and said predetermined depth falls with 1.27 to 2.54 cm of said surface.

It has been found that an optimum reduction of cellulite occurs by having 50% of the ultrasound energy transferred to the tissue within a depth of the human surface between 1.27 to 2.54 cm. This optimises the reduction of the cellulite because the ultrasound penetrates the tissue at the human surface to a prescribed depth such that most of the energy is transferred to the tissue at that depth rather than being transferred to deeper tissue. Generally, the ultrasound has a frequency tolerance of \pm .08 MHZ.

In one embodiment, the driving means comprises an oscillator means and an amplifier means; wherein the energy level control means alters the power output of the amplifier means to alter the level of driving of the ultrasound generator.

Thus, the level of energy can be simply and conveniently controlled.

Preferably, the apparatus further comprises pulse control means for controlling the drive means to modulate the
5 predetermined frequency in an ON/OFF fashion.

The use of ultrasound naturally causes some thermal warming effects which can clearly be detrimental as well as uncomfortable at the human surface concerned. By modulating the predetermined frequency in this way by means of the pulse
10 control means such detrimental effects can be decreased.

In one embodiment, the modulation of the predetermined frequency by the pulse control means is manually settable.

By having such modulation manually settable, it is possible to provide the operator of the apparatus with control
15 and flexibility over the way in which the ultrasonic energy is transferred to tissues enabling receptiveness to differing human surface types.

Conveniently, the pulse control means modulates the predetermined frequency at an ON/OFF frequency of 50 Hz.

20 By having a default value, the apparatus is automatically set to a preferred modulation for general operation whilst retaining flexibility of operation.

It is preferred that the pulse control means modulates the predetermined frequency in an ON/OFF fashion with a pulse
25 width ratio of 50 % \pm 20%.

This has been found to provide an optimum transfer of the ultrasound energy to the tissue without undue heating of the tissue.

Preferably, the apparatus further comprises switching
30 means for disconnecting said driving means from said ultrasound generator.

In this way, a simple control of the apparatus can be obtained in a convenient and cost effective manner.

In a preferred embodiment, the apparatus further
35 comprises timing means for controlling the drive means to drive the ultrasound generator for a predetermined time interval.

Thus, a particular length of time for the cellulite reduction can be set thereby freeing the operator of the apparatus to concentrate on the contact of the applicator means with the human surface.

5 Conveniently, said predetermined time interval in manually settable.

By having the predetermined time manually settable, it is possible to provide the operator of the apparatus with control and flexibility over the way in which the ultrasonic
10 energy is transferred to tissues according to differing amounts of cellulite present.

It is preferred that the apparatus further comprises means for calculating the amount of transfer of ultrasound vibrations between said human surface in contact with said
15 surface of the applicator means.

By monitoring the coupling between the applicator means and the human surface, it is possible for the operator to know how effective the transfer of ultrasound energy is to the tissue thereby enabling them to alter other variables if
20 necessary to compensate for coupling changes.

It is also preferred that the apparatus further comprises means for calculating the total amount of ultrasonic vibrations transferred to said human surface.

As a result, it is possible to keep records of the
25 amounts of ultrasonic energy transferred to the tissues to aid in evaluating the future requirements to reduce the cellulite.

According to another aspect of the present invention there is provided a non-invasive cellulite reduction apparatus comprising:-

30 an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations to a human surface in contact with a surface of the applicator
35 means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said

transferred ultrasound vibrations are absorbed within a predetermined depth of said human surface; and

a pulse control means for controlling the drive means to modulate the predetermined frequency in an ON/OFF fashion.

5 The use of ultrasound naturally causes some thermal warming effects which can clearly be detrimental as well as uncomfortable at the human surface concerned. By modulating the predetermined frequency in this way by means of the pulse control means such detrimental effects can be decreased.

10 Preferably, such modulation of the predetermined frequency by the pulse control means is manually settable.

Conveniently, the pulse control means modulates the predetermined frequency at an ON/OFF frequency of 50 Hz.

15 In one case, the pulse control means modulates the predetermined frequency in an ON/OFF fashion with a pulse width ratio of $50 \% \pm 20\%$.

20 An example of the present invention will now be described with reference to the single drawing which illustrates an ultrasound cellulite treatment apparatus embodying the present invention.

Referring to figure 1, a power circuit comprises a power supply 1 connected to a source of mains voltage M. The power supply 1 provides a 20 volt output which is supplied to a 5 volt DC regulator 2, a 12 volt DC regulator 3 and a variable
25 0 to 15 volt DC regulator 4. The regulator 2 provides a 5 volt output at terminal A and the regulator 3 provides a 12 volt output at terminal B. The regulator 4 provides an output signal on a line 33, the level of the signal being used so as to alter and control the magnitude or level of the ultrasonic
30 energy available an applicator head (not shown).

A driving means has a 4 MHZ reference crystal 23 to supply an output to a frequency synthesizer 24. A series of switches 22 supplied with 5 volts from terminal A are connected to the frequency synthesizer 24. Thus, the drive
35 frequency produced can be set to enable tuning to the natural frequency of an ultrasonic transducer in the applicator head. This generally factory set. The synthesizer output is supplied

through logic gating 21 to a power amplifier driver 19 powered by 12 volts from terminal B. The output of the power amplifier driver 19 is then supplied to an amplifier means in the form of a MOSFET power amplifier 18 which has an output magnitude controlled by the level of output signal appearing on the line 33. The magnitude of the output from the amplifier 18 controls the level of the ultrasonic energy available at the applicator head.

The output from the power amplifier 18 is passed through a 3.5 MHZ band pass filter 17 to a load impedance measuring circuit 34 before appearing as an output signal at an output terminal 35. The applicator head contains an ultrasonic generator in the form of a crystal which is connected to be oscillated by the output signal appearing at the terminal 35. It will be apparent that other forms of ultrasonic generation can be employed.

The level of the output signal appearing on line 33 controls the level of the ultrasound energy available at the applicator head. The signal on the line 33 is derived from an energy level control means in the form of a microprocessor 7 which is connected to a voltage to current converter 6 by a line 32 and then to the regulator 4 via a square root extractor 5. In this way, the voltage appearing on the line 32 is converted into a current and the square root of the magnitude of that current is supplied as a control signal to the regulator 4 to control the level of the output signal from the regulator 4 on line 33 and hence the level of the ultrasonic energy available at the applicator head.

A series of switches 8 supplied with 5 volts from terminal A are connected to the microprocessor 7 so as to provide a default setting for the level of the output signal from the regulator 4. However, a switch SE_{UP} and a switch SE_{DN} are provided for increasing or decreasing the voltage on line 32 so as to increase or decrease the level of the output signal of the regulator 4 and hence to increase or decrease the level of the ultrasonic energy available at the applicator head. The microprocessor 7 also provides a signal to a driver

9 so as to drive a display 10 to display the level of the ultrasonic energy available at the applicator head.

It can be seen therefore that the present invention provides a simple, efficient and effective way of controlling
5 the level of ultrasonic energy available at the applicator head for application to the skin so as to optimise the beneficial effects of the ultrasound energy interacting with the tissues containing cellulite.

To avoid heating of the skin or subcutaneous tissue, the
10 ultrasound energy is applied to the skin in an ON/OFF pulsed manner. This decreases the thermal effects from the ultrasound as much as possible without sacrificing the thrust of reducing cellulite. It has also been found that applying the ultrasound energy in this pulsed way improves the effectiveness of the
15 reduction of cellulite. Thus, a pulse control means is used to modulate the ultrasound energy available at the applicator head. This is an inventive concept in itself. The pulse control means has a microprocessor 29 which is connected to the logic gating 21 via a line 36. In this way, when the
20 appropriate gate value appears on line 36, the frequency output from the synthesizer 24 is passed to the power amplifier 19 and when the appropriate gate value does not appear on line 36, the frequency output from the synthesizer 24 is not passed to the power amplifier 19. Thus, the signal
25 appearing at the output 35 can be pulsed or modulated according to the control of the microprocessor 29.

A series of switches 36 supplied with 5 volts from terminal A are connected to the microprocessor 29 so as to provide a default setting for the pulse width of the signal
30 from the output 35. A frequency of 50 HZ is preferred with a default width generally set at 50%. However, a switch SP_{UP} and a switch SP_{DN} are provided for increasing or decreasing the width of pulses of signals at output 35.

The microprocessor 29 also provides a signal to a driver
35 30 so as to drive a display 31 to display the duty cycle of the ultrasonic energy available at the applicator head.

It can be seen therefore that the present invention

provides a simple, efficient and effective way of controlling the manner by which a predetermined amount of ultrasonic energy can be transferred to the tissues containing cellulite so as to optimise the beneficial effects of the reduction of cellulite by ultrasound.

It has been found that the time interval of application of ultrasound is important to the reduction in cellulite. Accordingly, a timing control means in the form of a microprocessor 26 is connected to the logic gating 21 via a line 37. In this way, when the appropriate gate value appears on line 37, the frequency output from the synthesizer 24 is passed to the power amplifier 19, subject to gating according to the gate value on line 36, and when the appropriate gate value does not appear on line 37, the frequency output from the synthesizer 24 is not passed to the power amplifier 19.

The gate value on line 37 is set to appear for a predetermined time according to a time setting once a start switch ST_s has been actuated. A series of switches 25 are connected to the microprocessor 26 so as to provide a default time setting. However, a switch ST_{up} and a switch ST_{DN} are provided for increasing or decreasing the default time setting. In this way, it is possible to control the length of time for which ultrasonic energy is applied to the skin and hence the dose of ultrasound energy applied to the skin. A further switch ST_F is connected to the microprocessor 26 for actively finishing or stopping the production of ultrasound energy and another switch ST_H is connected to the microprocessor 26 for temporarily halting or holding the production of ultrasound energy.

The microprocessor 26 also provides a signal to a driver 27 so as to drive a display 28 to display the available time remaining for application of the ultrasonic energy to the skin and also provides a 4 MHz clock output signal to a terminal output C .

It can be seen therefore that the present invention provides a simple, efficient and effective way of controlling

the time in which the ultrasonic energy can be applied to the skin so as to optimise the beneficial effects of the ultrasound treatment of cellulite.

This is also is an inventive concept in itself. Thus, a
5 transfer calculating means is provided which has takes a voltage output signal and a reflection signal from the load impedance measuring circuit 34 and supplies them to an analogue signal processing unit 16. This circuit provides a first output signal representative of the power passing to the
10 output 35 and a second signal representative of the coupling of the applicator head, essentially by monitoring the impedance of the electronics in the applicator head.

The first and second signals are supplied to a coupling calculation unit 13 which evaluates the amount of coupling.
15 This is then passed through a power switch 15 to a display 14 for displaying the current real time coupling of the applicator head to the skin. The power switch is controlled by signals appearing on line 37.

As stated above, to enable rigorous monitoring and
20 assessment of the correlation between applied ultrasound energy and cellulite reduction and to enable valid reproduction of cellulite, the total amount of ultrasonic energy transferred to the skin is very important.

Thus, a total transfer amount calculating means takes the
25 first and second signals from the analogue signal processing unit 16 and supplies them to a microprocessor 20 which, in response to the ON signal on line 37, starts to measure the total amount of energy being actually transferred to tissue, that is to say the amount of ultrasound energy transferred to
30 the skin. An output signal representative of this is sent via a multiplexer 12 to a display 11 for displaying the amount.

The apparatus of the present invention is operated as follows.

Initially, the operator of the apparatus sets an energy
35 value by means of the switches SE_{UP} and SE_{DN} according to the requirements of the skin region having the cellulite problem. Typically, 2.8 watts cm^2 is employed assuming use of a 100%

duty cycle. A maximum of 3 watts cm^2 is typically set by health and safety requirements. However, it should be noted that if the energy level is doubled, it has been found that the effects of cellulite are quadrupled due to a square law relationship between energy level and effectiveness.

Then, the operator sets the pulse rate by means of the switches SP_{UP} and SP_{DN} . Typically, a 50 Hz pulse rate is set with a pulse width ratio or duty cycle of $50\% \pm 20\%$.

Then, the operator sets a time for application of the ultrasound by means of the switches ST_{UP} and ST_{DN} . Typically, treatment times are increased linearly in time per treatment up to approximately 20 minutes. However, after 40 minutes, it has been found that treatment time becomes less effective.

It should be noted that research by the applicant has shown that it is important to use the correct amount of ultrasound energy for a particular human surface with results being proportional with the square of the power transferred into the tissue containing cellulite. In this respect, it is noted that it has been found that the average power is not the deciding factor, but the peak power delivered to the cellulite containing tissue. For example, if the pulse width ratio is 50%, effectively halving the average power, the treatment results decrease only approximately 20% compared with applying un-modulated ultrasound energy.

Thus, the energy level, pulse rate and time values are set and displayed on the respective displays. The operator then applies a suitable ultrasound transfer gel to the cellulite region to be treated and presses the applicator head to that region. Switch ST_s is then actuated and the application of ultrasound to the cellulite containing tissue starts. Immediately, the coupling of the ultrasound energy to the region is determined and displayed on display 14. At the same time, a cumulative amount of ultrasound energy is displayed on display 11. At the end of the time period set, the apparatus automatically stops generation of ultrasound energy and the total amount of ultrasound energy can be readily recorded from the display 11. A sound or light means

can be provided to indicate that the time has been completed.

If the application of ultrasound energy should need to be temporarily halted for some reason, then the operator actuates switch ST_H . Thus, it is possible to ensure that the
5 full required application of ultrasound energy can be applied. Similarly, if the treatment should need to be finished, then the operator actuates switch ST_F .

The applicator head is not illustrated in detail since it is an off the shelf applicator head. Nevertheless, it will
10 be appreciated that the synthesizer output 24 must be tuned to the natural frequency of the crystal in the applicator head to ensure accuracy determination of the coupling by the load impedance measuring circuit. If the tuning is not accurately
15 preset to the crystal, the values from this circuit are not reliable. The head comprises a piezo electric crystal to vibrate mechanically if a voltage with the correct frequency is applied. Thus, electrical power is transferred to sound power. The ultrasound vibration is transferred from the head
20 to the tissue using a stainless steel mechanical membrane with a wall thickness equal to a half wavelength which is glued to the crystal. It is preferred that a head with a modified lead zirconite titanate crystal transducer is installed since this has stable electrical properties with change of temperature
25 thereby enabling a reliable and accurate measurement of the impedance of the transducer for calculation of the coupling and amount of ultrasound energy transfer.

It is preferred that the impedance of the applicator head and the impedance of the power amplifier are such that the applied electrical power is automatically decreased if the
30 coupling to the cellulite tissue is not sufficient avoiding a rapid overheat of the applicator head if not correctly coupled.

Finally, a payment control circuit can be connected which is capable of disabling the microprocessor 26. The payment
35 control circuit can be designed to require a code to be entered before the apparatus will operate and which will disable the microprocessor 26 once a specified time of

ultrasound application has been used. In this way, a predetermined amount of time of ultrasound energy production can be purchased.

5 It will be understood that the embodiment illustrated shows an application of the invention in one form only for the purposes of illustration. In practice, the invention may be applied to many different configurations, the detailed embodiments being straightforward for those skilled in the art to implement. For example, whilst the present invention shows
10 various components as separate, it would be possible to arrange the components in a more integral form.

CLAIMS

1. A non-invasive cellulite reduction apparatus comprising:-

5 an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations to a human surface in contact with a surface of the applicator
10 means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said transferred ultrasound vibrations are absorbed within a predetermined depth of said human surface; and

15 energy level control means for controlling the magnitude of said ultrasound vibrations.

2. Apparatus according to claim 1 wherein said predetermined frequency is manually settable.

3. Apparatus according to claim 1 or 2 wherein the
20 predetermined frequency has a value of $3.3 \text{ MHz} \pm 0.5 \text{ MHz}$.

4. Apparatus according to any preceding claim wherein said major portion comprises 50% and said predetermined depth falls within 1.27 to 2.54 cm of said surface.

5. Apparatus according to any preceding claim wherein
25 the driving means comprises an oscillator means and an amplifier means; wherein the energy level control means alters the power output of the amplifier means to alter the level of driving of the ultrasound generator.

6. Apparatus according to any preceding claim further
30 comprising pulse control means for controlling the driving means to modulate the predetermined frequency in an ON/OFF fashion.

7. Apparatus according to claim 6 wherein the modulation of the predetermined frequency by the pulse control
35 means is manually settable.

8. Apparatus according to claim 6 or 7 wherein the pulse control means modulates the predetermined frequency at

an ON/OFF frequency of 50 Hz.

9. Apparatus according to any one of claims 6 to 8 wherein the pulse control means modulates the predetermined frequency in an ON/OFF fashion with a pulse width ratio of 50
5 $\pm 20\%$.

10. Apparatus according to any preceding claim further comprising switching means for disconnecting said driving means from said ultrasound generator.

11. Apparatus according to any preceding claim further
10 comprising timing means for controlling the drive means to drive the ultrasound generator for a predetermined time interval.

12. Apparatus according to claim 11 wherein said predetermined time interval is manually settable.

13. Apparatus according to any preceding claim further
15 comprising means for calculating the amount of transfer of ultrasound vibrations between said human surface in contact with said surface of the applicator means.

14. Apparatus according to any preceding claim further
20 comprising means for calculating the total amount of ultrasonic vibrations transferred to said human surface.

15. A non-invasive cellulite reduction apparatus comprising:-

25 an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations to a human surface in contact with a surface of the applicator
30 means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said transferred ultrasound vibrations are absorbed within a predetermined depth of said human surface; and

35 a pulse control means for controlling the drive means to modulate the predetermined frequency in an ON/OFF fashion.

16. Apparatus according to claim 15 wherein the

modulation of the predetermined frequency by the pulse control means is manually settable.

17. Apparatus according to claim 15 or 16 wherein the pulse control means modulates the predetermined frequency at
5 an ON/OFF frequency of 50 Hz.

18. Apparatus according to any one of claims 15 to 17 wherein the pulse control means modulates the predetermined frequency in an ON/OFF fashion with a pulse width ratio of 50 % \pm 20%.

10 19. A non-invasive cellulite reduction apparatus substantially as herein described with reference to the accompanying drawing.